UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Review of efficacy data submitted by Avon Products, Inc. in support of registering Avon Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellents. EPA Reg Nos 806-ER, 806-RO, 806-EN; Barcode No. D277712; Case No. 070186; Submission No. S602575; Chemical No. 113509; MRID Nos. 453533-04, 453533-05, 453533-06, 454767-01, 454767-02, 454743-01, 453591-04, 453591-05, 453591-06, 453591-07, 453590-06, 453590-07, 453590-08, 453590-09, 454760-01.

To: Jim Downing, Regulatory Action Leader
Biopesticides and Pollution Prevention Division, 7511C

From: Robyn Rose, Entomologist
Biopesticides and Pollution Prevention Division, 7511C

Classification: All submissions for Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent SPF 15 Sunscreen- Pump Spray (EPA Reg No 806-RO) and Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent-Pump Spray; (EPA Reg No 806-ER) are **unacceptable** because efficacy tests were not conducted with the end-use product.

All submissions for Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray (EPA Reg No 806-EN) are **acceptable**. Submitted studies support a label claim of 8 hours of repellency for mosquitoes and deer ticks and 4 hours of repellency for black flies, gnats, biting midges, sand flies and no-seeums.

BACKGROUND

IR3535 is a currently registered active ingredient used in insect repellents. IR3535, (3-[N-Butyl-N-acetyl]-aminopropionic acid, ethyl ester, occurs naturally. The active ingredient is a liquid at room temperature. Avon has submitted a request to register three formulations of Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent. The three formulations include a pump spray with SPF 15 sunscreen, a pump spray without sunscreen and an aerosol spray without sunscreen. The pump sprays contain 15.0% of the active ingredient and the aerosol spray contains 20.07% of the active ingredient. EPA has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control termites or pests that

pose a threat to human health (OPPTS 810.3000). The product performance requirements for public health uses include those for mosquitoes, black flies (gnats), biting midges (no-seeums), sand flies and deer ticks. Pest Registration Notice (PRN) 2002-1 provides a list of pests of significant public health importance

The pump spray formulations claim to repel mosquitoes for 8 hours and deer ticks for 6 hours on the label. The directions for use section of the pump sprays also state continued protection against gnats, no-seeums, sand flies and biting midges for 8 hours and black flies for 4 hours. The aerosol spray formulations claim to repel mosquitoes and deer ticks for 8 hours on the label. The directions for use section of the aerosol states that there is continued protection from black flies, gnats, no-seeum, sand flies and biting midges for 6 hours. Efficacy data is routinely reviewed by the Agency when a product claims to repel a potential vector. EPA defines a vector as any organism that can cause or transmit human disease, or can cause human discomfort or injury. Therefore, efficacy data was submitted to the Agency for review to support registration of the three formulations of Skin-So-Soft Bug Guard Plus IR3535.

CONCLUSIONS

Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent SPF 15 Sunscreen- Pump Spray; EPA Reg No 806-RO

Black Flies (MRID 453533-06)

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from black flies. Therefore, this test should be repeated in two locations using the end-use product.

Mosquitoes (MRID 453533-05 and 453533-04)

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product.

Biting Midges, No-seeums, Sand Flies (MRID 454767-02)

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from biting midges. Therefore, this test should be repeated in two locations with a biting pressure of at least one biting midge per five minutes of exposure.

Deer Ticks (MRID 454743-01)

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 15 Insect Repellent Pump Spray Formula 16684-01 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from deer ticks. Therefore, this test should be repeated with Skin-So-Soft Bug Guard Plus IR3535® Insect Repellent SPF 15.

<u>Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent- Pump Spray; EPA Reg No 806-ER</u>

Deer Ticks (MRID 454767-01)

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from deer ticks. Therefore, this test should be repeated with Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent.

Biting Midges, No-seeums, Sand Flies (MRID 453591-07)

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance

affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from mosquitoes. Therefore, this test should be repeated in two locations using the end-use product in areas with a biting pressure of at least one bite/land per five minute exposure period.

Mosquitoes (MRID 453591-04 and 453591-05)

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product.

Black Flies, Gnats (MRID 453591-06)

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have no affect on protection from black flies. Therefore, this test should be repeated in two locations using the end-use product in areas with a biting pressure of at least five bites/lands per five minute exposure period.

<u>Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray (EPA Reg No 806-EN)</u>

Black Flies, Gnats (MRID 453590-08)

The results of this study indicate that the test material at the dosage tested provides an average protection time against black flies of at least four hours based on the average time to first bite. Insect repellent efficacy tests should be based on the average time to the first bite or the time to a 95% reduction in bites. This study does not verify that 16360-23 (D) Aerosol will provide protection from black flies for 6 hours as the label states. According to PR Notice 2002-1 black flies and gnats are both in the family Simuliidae. These common names are often used for the same insects. Based on the submitted information, the label should recommend reapplying 16360-23 (D) Aerosol every 4 hours for protection from black flies and/or gnats.

Biting Midges, No-Seeums, Sand Flies (MRID 453590-09)

It can be concluded from this study that 16360-23 (D) Aerosol will provide an average of four hours of protection from biting midges. Therefore the label should recommend reapplication of Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray every four hours for protection against biting midges. Since sand flies and no-seeums are considered synonymous common names to biting midges, it is also acceptable to claim four hours of repellency against these insects.

Mosquitoes (MRID 453590-06 & 453590-07)

The results of MRID 453590-07 indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray claims an eight hour repellency against mosquitoes and is acceptable.

The product label submitted with MRID 45359006 claims an eight hour repellency against mosquitoes. Although the average time to first bite reported in Table 1 was slightly less than 8 hours, it can be assumed that an average time to first bite was at least 8 eight post application since five treated arms and four treated legs provided >8 hours of protection from mosquito bites. The results of this study indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray claims an eight hour repellency against mosquitoes and is acceptable.

Deer Ticks (MRID 454760-01)

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The results of the study indicate that the test material at the dosage tested is effective in repelling ticks from human skin for a minimum of four hours, and in most subjects for eight hours. This exceeds the minimum acceptable protection time of one hour specified in OPPTS 810.3300. The product label submitted for Insect Repellent Aerosol Spray Formula No. 16360-23 claims an eight-hour repellency for deer ticks. This test resulted in a >95% repellency of deer ticks for eight hours. Therefore, it is acceptable to state an eight-hour duration of repellency on the Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray label.

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Fr e B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45353306
TEST MATERIAL:	16684-01 (B) SPF 15 Pump
STUDY NO:	16684-01 (B) SPF 15 Pump
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228-1199
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Black Flies
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 6, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

OBJECTIVE:

This study was conducted to evaluate the efficacy of four formulations of insect repellent containing IR3535 as the active ingredient against black flies, *Simulium* spp. in Maine

TEST METHOD

Field tests were conducted near Lake Nicatous, Maine to determine the efficacy of 16684-01 (B) SPF 15 Pump to repel black flies (primarily *Simulium aureum* and *Prosimulium multidentatum*). Eight-hour tests were conducted on two consecutive days, using 10 different test subjects and 2 control subjects each day. The night before testing, subjects shoes were treated with Permonone® (0.k5% permethrin aerosol) to repel ticks. Subjects wore socks during testing and a 400 cm^2 area of exposed skin below one knee of each subject was treated with 0.81 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin below the knee of 2 control subjects was exposed for 5 minutes at approximately 30 intervals throughout the test period to verify biting pressure remained at 1-5/minute. Additionally, a whole-body count of black fly landings (time not specified) on one of the control subjects was taken at the beginning of the study and hourly

thereafter. Subjects with treated legs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two fly landings occurring within 30 minutes of each other. The second fly landing is considered a "confirmatory landing." A landing was defined as a fly remaining on the skin for at least 2 seconds. Test subjects moved about an area in pairs remaining approximately 1-2 meters apart. Data was reported as the average amount of time in hours and minutes to test termination.

RESULTS SUMMARY

On control subjects, flies landed at a rate of 3 to 33 times per 5-minute exposure period. Breakdown occurred within eight hours on 17 of the 20 test subjects over the two days (Table 1). The three remaining subjects experienced at least one fly landing, but not within 30 minutes of a second landing. On Day 1, the breakdown time ranged from 24 minutes to >8 hours, with an average of 3 hours and 37 minutes. On Day 2, breakdown time ranged from 13 minutes to >8 hours, with an average of 4 hours and 15 minutes. Fly landings on the control subjects ranged from 3 to 24/five-minute exposure on Day 1, and from 3 to 33 landings/five-minute exposure on Day 2. Whole body counts for the control subjects ranged from 18 to 33 landings/minute on Day 1, and from 32 to 63 landings/minute on Day 2.

Table 1. Fly landing times

Test subject	Breakdown time	Time of first landing
Day 1		
1	1 hr 9 min	0 hr 31 min
2	5 hr 54 min	0 hr 32 min
3	>8 hr	3 hr 17 min
4	0 hr 35 min	0 hr 35 min
5	0 hr 24 min	0 hr 24 min
6	2 hr 39 min	2 hr 39 min
7	3 hr 55 min	1 hr 13 min
8	4 hr 3 min	2 hr 47 min
9	1 hr 30 min	1 hr 30 min
10	>8 hr	0 hr 36 min
Mean	3 hr 37 min	1 hr 24 min

Day 2		
1	1 hr 34 min	0 hr 12 min
2	7 hr 51 min	7 hr 51 min
3	0 hr 13 min	0 hr 13 min
4	5 hr 37 min	5 hr 37 min
5	5 hr 16 min	0 hr 7 min
6	4 hr 48 min	3 hr 5 min
7	>8 hr	>8 hr
8	3 hr 22 min	3 hr 22 min
9	0 hr 18 min	0 hr 18 min
10	5 hr 29 min	0 hr 25 min
Mean	4 hr 15 min	2 hr 55 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that Skin-So-Soft Bug Guard Plus IR3535 SPF 15 Pump Spray provided good overall protection from black fly landings, with an average protection time of 3 hours and 37 minutes on Day 1 and 4 hours and 15 minutes on Day 2.

REVIEWER'S COMMENTS

In two 8-hour field tests using human subjects, 16684-01 (B) SPF 15 Pump was evaluated for protection from black flies (*S. aureum* and *P. multidentatum*). According to results submitted to the Agency, on Day 1, the mean protection time was 3 hours and 37 minutes; on Day 2, it was 4 hours and 15 minutes. The average duration of repellency for the two tests is 3 hours and 93 minutes.

The study author noted that there were four 5-minute exposure periods on Day 1 and one on Day 2 when the rate of five landings in five minutes recommended by OPPTS 810.3700 (Draft) was not achieved by one of the two control subjects. However, in each case the other control subject did achieve at least that rate, and none of the low rates occurred during consecutive test periods or during the last hour of either day, when the test material would have been least effective. The overall landing rate was therefore considered acceptable. The product label claims a four hour repellency against black flies.

To verify efficacy of a repellent against black flies, at least two distinct field sites should be

tested. In addition, tests should be based on a 95% reduction in bites rather than the time until two bites are reached in 30 minutes. If a second bite is not received within 30 minutes of the first bite, then the bite is ignored and the test continues. No bites should be ignored during an efficacy test. Based on this test, it is likely that the duration of effective repellency is < 4 hours.

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from black flies. Therefore, this test should be repeated in two locations using the end-use product.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45353306

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 95

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 10 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature:
Date: APR

Robert H. Ross, M.S., Group Leader

Signature:
Date: APR 10 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 10 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45353305
TEST MATERIAL:	16684-01 (B) SPF 15 Pump
STUDY NO	0400-059-0077 (B)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228-1199
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 8, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

An eight-hour field test using 10 human volunteers was conducted in Butterfield Island, Maine to determine the efficacy of 13349-14 (A) SPF 15 Pump to repel mosquitoes (primarily *Aedes intrudens*). The night before testing, subjects shoes were treated with Permonone® (0.5% permethrin aerosol) to repel ticks. Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.51 mL of the test material (1.7 mg/cm^2), making a total of 20 test areas. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals throughout the test to verify adequate biting pressure in the area. One of the controls also received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Treated limbs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as a bite followed by a second bite within 30 minutes of the initial bite. The second bite is considered a "confirmatory" bite.

RESULTS SUMMARY

There was no breakdown on any of the 20 test sites at any time during the test (Table 1). The control whole-body mosquito landing count ranged from 25 to 77/minute, while landings on control legs ranged from 5 to 63/five minutes.

TABLE 1. Mosquito biting times

Test subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	>8 hr	>8 hr
1/leg	>8 hr	>8 hr
2/arm	>8 hr	>8 hr
2/leg	>8 hr	>8 hr
3/arm	>8 hr	> 8 hr
3/leg	>8 hr	>8 hr
4/arm	>8 hr	>8 hr
4/leg	>8 hr	>8 hr
5/arm	>8 hr	>8 hr
5/leg	>8 hr	2 hr 54 min
6/arm	>8 hr	>8 hr
6/leg	>8 hr	>8 hr
7/arm	>8 hr	>8 hr
7/leg	>8 hr	>8hr
8/arm	>8 hr	>8 hr
8/leg	>8 hr	>8 hr
9/arm	>8 hr	>8 hr
9/leg	>8 hr	>8 hr
10/arm	>8 hr	>8 hr
10/leg	>8 hr	>8 hr
Mean	> 8hr	7 hr 45 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 13349-14 (A) SPF 15 Pump provided complete eight-hour protection from mosquito bites for 20 of the 20 test areas

REVIEWER'S CONCLUSIONS

In a field test, 13349-14 (A) SPF 15 Pump provided protection from mosquito bites on 10 subjects for slightly less than 8 hours. The control whole-body mosquito landing count ranged from 25 to 77/minute, while landings on control legs ranged from 5 to 63/five minutes. OPPTS 810.3300 states that a mosquito repellent should generally provide a minimum of 2-3 hours protection time, depending on the biting pressure. The results of this study indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for 13349-14 (A) SPF 15 Pump claims an eight-hour repellency against mosquitoes. Duration of repellency should be based on time to first bite or 95% reduction in bites. The raw data shows that the time to first bite is slightly less than 8 hours; however, at least a 95% reduction in bites was achieved at 8 hours post treatment.

To verify efficacy of a mosquito repellent, at least two studies in environmentally distinct areas should be conducted with mosquitoes from at least two Genuses. Therefore, an additional acceptable study in an area with adequate mosquito biting pressure should be conducted to verify the efficacy of 13349-14 (A) SPF 15 Pump.

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45353305

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 95

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 10 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature:
Date: APR 10 2002

Robert H. Ross, M.S., Group Leader

Signature:
Date: APR 10 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date:

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45353304
TEST MATERIAL:	16684-01 (B) SPF 15 Pump
STUDY NO:	0400-059-0078 (B)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern NY 10901-5605
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228-1199
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	January 30, 2001
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

An eight-hour field test using 10 human volunteers was conducted at Stuttgart High School in Stuttgart, Arkansas to determine the efficacy of 16684-01 (B) SPF 15 Pump to repel mosquitoes (primarily *Anopheles quadrimaculatus* and *Psorophora columbiae*). The night before testing, subjects shoes were treated with Permonone® (0.5% permethrin aerosol) to repel ticks. Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.51 mL of the test material (1.7 mg/cm^2), making a total of 20 test areas. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals until the late stages of the test, during which exposure was continuous to verify adequate biting pressure at the testing location. One of the controls also received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Control landings were monitored for 8.5 hours. Previous monitoring had determined that the mosquitoes were only active for about one hour, with landing rates of 1 to 10 per minute during that period. Therefore, to determine repellency up to eight hours after application, the test material was

applied seven hours prior to the expected activity period. Subjects with treated limbs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two mosquito bites occurring within a thirty-minute period.

RESULTS SUMMARY

There was no breakdown on 18 of the 20 test areas, with 14 of those 18 receiving no bites at all (Table 1). For the remaining 2 limbs, breakdown times were 6 hours and 58 minutes and 7 hours and 17 minutes. No protection was claimed for those areas since breakdown occurred prior to the period of high mosquito activity. The control whole-body mosquito landing count was 0 for the first 7 hours of the test, increasing to 45 landings at 8 hours and 57 at 8.5 hours. Control legs (combined) had comparable activity, with a total of 2 landings/5 minutes at 7 hours, 5 landings/five minutes at 7.5 hours, 51 landings/five minutes at 8 hours, and 41 landings/five minutes at 8.5 hours.

TABLE 1. Mosquito biting times

Test subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	>8 hr	7 hr 49 min
2/arm	>8 hr	>8 hr
3/arm	>8 hr	> 8 hr
4/arm	>8 hr	>8 hr
5/arm	>8 hr	>8 hr
6/arm	>8 hr	>8 hr
7/arm	>8 hr	>8 hr
8/arm	>8 hr	>8 hr
9/arm	>8 hr	7 hr 50 min
10/arm	7 hr 17 min	7 hr 17 min
Avg/arm	7 hr 55 min	7 hr 51 min
1/leg	>8 hr	6 hr 16 min
2/leg	>8 hr	>8 hr
3/leg	6 hr 58 min	6 hr 58 min

Test subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
4/leg	>8 hr	>8 hr
5/leg	>8 hr	>8 hr
6/leg	>8 hr	7 hr 44 min
7/leg	>8 hr	>8hr
8/leg	>8 hr	>8 hr
9/leg	>8 hr	>8 hr
10/leg	>8 hr	>8 hr
Avg/leg	7 hr 51 min	7 hr 39 min
Avg/arm & leg	7 hr 53 min	7 hr 46 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 13349-14 (A) SPF 15 Pump provided complete eight-hour protection from mosquito bites for 18 of the 20 test sites. It was noted that the test subjects perspired profusely during the entire test period due to extreme temperature (83-96°F) and humidity (66-86%). As a result, some of the repellent may have washed from the subjects' skin, contributing to the two breakdowns seen in this study.

REVIEWER'S CONCLUSIONS

OPPTS 810.3300 states that a product should generally provide a minimum of 2-3 hours protection time against mosquitoes, depending on the biting pressure. The test material in this study had to be applied well before the time of peak mosquito activity because the landing rate of five landings in five minutes recommended by OPPTS 810.3700 (Draft) on the control subjects was not achieved for most of the test period. The recommended biting pressure of 5 landings/5 minutes only occurred eight hours after application of the test material.

Duration of repellency should be based on time to first bite or 95% reduction in bites. It is difficult to interpret the submitted data based on a 95% reduction in bites; therefore, duration of repellency should be based on the average time to first bite. The average time to first bite in this study was approximately 7 hours and 46 minutes from test initiation. However, this data is insufficient to conclude a duration of repellency since biting pressure was only adequate at approximately the same time the repellent failed. Therefore, additional studies are needed to determine duration of effective repellency for 13349-14 (A) SPF 15 Pump.

Efficacy tests should be conducted with the end-use product. This test was conducted with

16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45353304

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 95

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 10 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature:
Date: APR 10 2002

Robert H. Ross, M.S., Group Leader

Signature:
Date: APR 10 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 10 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45476702
TEST MATERIAL:	16684-01 (B) SPF 15 Pump
STUDY NO:	0400-059-0079 (B)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228-1199
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Biting Midges
AUTHOR(S):	Niketas C. Spero
STUDY COMPLETED:	January 31, 2001
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

Two field tests were conducted in Conifer Lake, Pine Island, Florida to determine the efficacy of 16684-01 (B) SPF 15 Pump to repel biting midges (primarily *Culicoides furens* and *C. barbosai*). Eight-hour tests were conducted on two consecutive days, using ten volunteers each day. A 250 cm^2 area of exposed skin on one arm of each subject was treated with 0.51 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one arm of two additional control subjects was exposed for five minutes at thirty-minute intervals until the midge landing rate had peaked, after which exposure was continuous. Previous monitoring had determined that peak midge activity was limited to an approximate two-hour window. Therefore, to determine repellency

eight hours after application, the test material was applied at least six hours prior to expected peak midge activity. However, midge activity during the last two hours of testing (peak activity) did not reach one land per minute; therefore, midge activity was continuously monitored rather than conducting five minute counts every hour. Subjects with treated arms were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two midge bites occurring within a thirty-minute period.

RESULTS SUMMARY

According to the study author, no breakdowns occurred on any subject during either test session. However, an "unconfirmed" bite (no second bite occurring within the 30 minutes of the first bite) occurred on one test subject each day. There was little midge activity during the first six hours of the test. Activity increased during the final two hours, but was still generally below 1 landing/minute. On Day 1, one control recorded 17 landings during the final one and one-half hours of the test; the other control recorded 8 landings. On Day 2, one control recorded 35 landings in the final 65 minutes of the test; the other recorded 71 landings in the final 69 minutes.

Table 1. Bite Times (Session 1) Heliopad, Pine Island, Florida

Test Subject	Time of First Confirmed Bite (Hrs & Min)	Time of First Bite (Hrs & Min)
1	> 8 hr - 0 min	> 8 hr - 0 min
2	> 8 hr - 0 min	> 8 hr - 0 min
3	> 8 hr - 0 min	> 8 hr - 0 min
4	> 8 hr - 0 min	> 8 hr - 0 min
5	> 8 hr - 0 min	> 8 hr - 0 min
6	> 8 hr - 0 min	> 8 hr - 0 min
7	> 8 hr - 0 min	> 8 hr - 0 min
8	> 8 hr - 0 min	5 hr - 14 min
9	> 8 hr - 0 min	> 8 hr - 0 min
10	> 8 hr - 0 min	> 8 hr - 0 min
Avg	> 8 hr - 0 min	7 hr - 43 min

Table copied from pg 9 of 131 in MRID No 454767-02

Table 1. Bite Times (Session 3) Conifer Lake, Pine Island, Florida

Test Subject	Time of First Confirmed Bite (Hrs & Min)	Time of First Bite (Hrs & Min)
1	> 8 hr - 0 min	> 8 hr - 0 min
2	> 8 hr - 0 min	> 8 hr - 0 min
3	> 8 hr - 0 min	> 8 hr - 0 min
4	> 8 hr - 0 min	> 8 hr - 0 min
5	> 8 hr - 0 min	> 8 hr - 0 min
6	> 8 hr - 0 min	> 8 hr - 0 min
7	> 8 hr - 0 min	6 hr - 49 min
8	> 8 hr - 0 min	> 8 hr - 0 min
9	> 8 hr - 0 min	> 8 hr - 0 min
10	> 8 hr - 0 min	> 8 hr - 0 min
Avg	> 8 hr - 0 min	7 hr - 53 min

Table copied from pg 10 of 131 in MRID No 454767-02

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that, at the population densities in the test areas, 16684-01 (B) SPF 15 Pump provided complete protection from midge bites for all subjects at both locations during both days of testing.

REVIEWER'S CONCLUSIONS

In two 8-hour field tests using human subjects, 16684-01 (B) SPF 15 Pump was evaluated for protection against biting midges (*Culicoides furens* and *C. barbosai*). OPPTS 810.3300 states that a product may be registered for repelling biting flies (including midges) if it provides 1 to 3 hours of protection. A biting pressure of at least one landing in five minutes is recommended by OPPTS 810.3700 (Draft). The recommended landing rate was achieved during the last hour or more of testing on Day 2 (Session 3), but did not occur on Day 1 (Session 1) of testing. It is acceptable that the test material was applied so that peak midge activity occurred during the end of the test period when the repellent would be expected to be least effective.

This test was conducted based on the "first confirmed bite test". Tests should be conducted based on a 95% reduction in bites. Based on the raw data provided, it can be concluded that 95% reduction in bites was achieved during this study. Although at least a 95% reduction in bites was achieved on the treated test subjects, biting pressure was only acceptable during Day 2 of testing.

Since the overall landing rate was only acceptable for one test, a second test should be conducted to verify the efficacy of 16684-01 (B) SPF 15 Pump for an eight-hour repellency against biting midges.

Efficacy tests should be conducted with the end-use product. This test was conducted with 16684-01 (B) SPF 15 Pump which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from biting midges. Therefore, this test should be repeated in two locations with a biting pressure of at least one biting midge per five minutes of exposure.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45476702

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 95

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 10 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: Patricia H. Reno
Date: APR 10 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 10 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 10 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45474301
TEST MATERIAL:	SPF 15 Insect Repellent Pump Spray Formula 16684-01
STUDY NO:	AV0002b
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Benzon Research, 208 Burnt House Rd, Carlisle, PA 17013
TITLE OF REPORT:	Repellency of Avon SPF 15 Insect Repellent Pump Spray Against Nymphal *Ixodes scapularis* Ticks
AUTHOR:	Gary L. Benzon, Ph.D
STUDY COMPLETED:	December 15, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	The study was conducted in compliance with 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

Laboratory tests were conducted to determine the efficacy of Avon SPF 15 Insect Repellent Pump Spray Formula 16684-01 to repel the movement of nymphal deer ticks (*Ixodes scapularis*) onto human skin. A 25 cm^2 area of skin on the medial forearm of 10 volunteers was treated with 42.5 mg of the test material (1.7 mg/cm^2). Just prior to treatment, the test material was sprayed into a container, applied using a variable pipette, and evenly spread across the test area. A similar area of untreated skin served as a control. The ticks were placed in test plates fabricated from polystyrene Petri dish lids with a 2.54-cm diameter hole in the center of the lid. A removable patch of paper towel was used to prevent ticks from escaping through the hole between challenges.

At 60-minute intervals over 8 hours (two subjects were tested every 30 minutes for the first four hours and every 60 minutes thereafter) the treated and control areas were each challenged by placing a test plate containing 10±2 ticks onto the skin for 60 seconds, and the number of tick contacts was determined. A contact was counted if the tick moved from the test plate completely onto the skin exposed through the hole in the center of the test plate and remained there for at least five seconds. Ticks that remained on the skin for at least five seconds but exhibited certain retreat behaviors, e.g., rapid movement with multiple direction changes and immediate exit upon re-contacting the plate, were not counted as contacts. At the end of the 60-second challenge, the plate was removed from the skin and any ticks remaining on the skin were returned to the test plate.

RESULTS SUMMARY

The test material provided 100% repellency against deer ticks for all subjects up to four hours post-treatment, and for two subjects up to eight-hours post-treatment (Table 1). During hours five through eight, repellency ranged from 20.5-100% among all subjects. Ticks crawled without hesitation onto the untreated skin of all subjects.

TABLE 1. Percent repellency of Formula 16684-01

		Hours Post-Treatment							
Test subject	$CP_{control}$[a]	1	2	3	4	5	6	7	8
1	56.3	100	100	100	100	100	100	100	100
2	41.4	100	100	100	100	87.9	100	87.9	100
3	50.6	100	100	100	100	100	100	100	80.2
4	40.9	100	100	100	100	100	100	100	87.8
5	42.5	100	100	100	100	100	100	88.2	88.2
6	40.9	100	100	100	100	100	87.8	87.8	100
7	45.6	100	100	100	100	100	100	78.1	78.1
8	50.3	100	100	100	100	70.2	80.1	20.5	22.7
9	45.0	100	100	100	100	100	88.9	88.9	77.8
10	45.3	100	100	100	100	100	89.0	100	100
Mean		100	100	100	100	95.8	94.6	95.1	93.5

[a]Control Contact Percentage ($Cp_{control}$) for each subject = sum of ticks on control skin ÷ sum of ticks exposed to control skin x 100

% Repellency for any post-treatment interval = 100 - (sum of contacts on treated skin ÷ sum of ticks exposed to treated skin x 10,000) [illegible]

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that SPF 15 Pump Spray Formula 16684-01 was completely effective in preventing deer tick movement onto treated skin for at least four hours post-treatment, and that on average, repellency remained high for the remainder of the eight-hour test period.

REVIEWER'S CONCLUSIONS

SPF 15 Insect Repellent Pump Spray Formula 16684-01 was 100% effective for a minimum of four hours in repelling the movement of nymphal deer ticks onto the treated skin of ten human volunteers. In hours five to eight of the test, repellency ranged from 20.5-100% among all subjects. Ticks crawled without hesitation onto the untreated skin of all controls.

The results of this study indicate that the test material at the dosage tested is effective in repelling ticks from human skin for up to seven hours. This exceeds the minimum acceptable protection time of one hour specified in OPPTS 810.3300. The product label submitted for SPF 15 Insect Repellent Pump Spray Formula 16684-01 claims a six-hour repellency for deer ticks. Since at least 95% protection from deer ticks has been demonstrated, it is acceptable to claim six hours of repellency on the SPF 15 Insect Repellent Pump Spray Formula 16684-01.

However, efficacy tests should be conducted with the end-use product. This test was conducted with SPF 15 Insect Repellent Pump Spray Formula 16684-01 which is not identical to Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15 was not added to 16684-01 (B) SPF 15 Pump. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from deer ticks. Therefore, this test should be repeated with Skin-So-Soft Bug Guard Plus IR3535 Insect Repellent SPF 15.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300
MRID 45474301

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 96

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 12 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: Patricia H. Reno
Date: APR 12 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 12 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 12 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45476701
TEST MATERIAL:	SPF 0 Insect Repellent Pump Spray Formula 13349-14
STUDY NO:	AV0002a
SPONSOR:	Avon Products, Inc. , Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Benzon Research, 208 Burnt House Rd, Carlisle, PA 17013
TITLE OF REPORT:	Repellency of Avon SPF 0 Insect Repellent Pump Spray Against Nymphal *Ixodes scapularis* Ticks
AUTHOR:	Gary L. Benzon, Ph.D.
STUDY COMPLETED:	December 15, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	The study was conducted in compliance with 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

Laboratory tests were conducted to determine the efficacy of Avon SPF 0 Insect Repellent Pump Spray Formula 13349-14 to repel the movement of nymphal deer ticks (*Ixodes scapularis*) onto human skin. A 25 cm^2 area of skin on the medial forearm of 10 human volunteers was treated with 42.5 mg of the test material (1.7 mg/cm^2). Just prior to treatment, the test material was sprayed into a container, applied using a variable pipette, and evenly spread across the test area. A similar area of untreated skin served as a control. The ticks were placed in test plates fabricated from polystyrene Petri dish lids with a 2.54-cm diameter hole in the center of the lid. A removable patch of paper towel was used to prevent ticks from escaping through the hole between challenges.

At 60-minute intervals over 8 hours (two subjects were tested every 30 minutes for the first four hours and every 60 minutes thereafter) the treated and control areas were each challenged by placing a test plate containing 10±2 ticks onto the skin for 60 seconds, and the number of tick contacts was determined. A contact was counted if the tick moved from the test plate completely onto the skin exposed through the hole in the center of the test plate and remained there for at least five seconds. Ticks that remained on the skin for at least five seconds but exhibited certain retreat behaviors, e.g., rapid movement with multiple direction changes and immediate exit upon re-contacting the plate, were not counted as contacts. At the end of the 60-second challenge, the plate was removed from the skin and any ticks remaining on the skin were returned to the test plate.

RESULTS SUMMARY

The test material provided 100% repellency against deer ticks for all subjects up to four hours post-treatment, and for two subjects up to eight-hours post-treatment (Table 1). During hours five through eight, the mean repellency was 82-99%. Ticks crawled without hesitation onto the untreated skin of all subjects.

TABLE 1. Percent repellency of Formula 13349-14

		Hours Post-Treatment							
Test subject	$CP_{control}$[a]	1	2	3	4	5	6	7	8
1	56.3	100	100	100	100	100	100	100	100
2	41.4	100	100	100	100	100	100	100	100
3	50.6	100	100	100	100	100	100	100	90.1
4	40.9	100	100	100	100	100	100	100	75.5
5	42.5	100	100	100	100	100	100	100	88.2
6	40.9	100	100	100	100	100	87.8	87.8	100
7	45.6	100	100	100	100	100	100	78.1	78.1
8	50.3	100	100	100	100	90.1	60.3	20.5	10.6
9	45.0	100	100	100	100	100	100	88.9	77.8
10	45.3	100	100	100	100	100	100	100	100
Mean		100	100	100	100	99.0	94.8	87.5	82.0

[a] Control Contact Percentage ($Cp_{control}$) for each subject = sum of ticks on control skin ÷ sum of ticks exposed to control skin x 100

% Repellency for any post treatment interval = 100 - (sum of contacts on treated skin ÷ sum of ticks exposed to treated skin x 100)

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that SPF 0 Pump Spray Formula 13349-14 was completely effective in preventing deer tick movement onto treated skin for at least four hours post-treatment, and that the average repellency was high for the remainder of the eight-hour test period.

REVIEWER'S CONCLUSIONS

The results of the study indicate that the test material at the dosage tested is 100% effective in repelling ticks from human skin for a minimum of four hours. This exceeds the minimum acceptable protection time of one hour specified in OPPTS 810.3300. SPF 0 Insect Repellent Pump Spray Formula 13349-14 was 100% effective for four hours in repelling the movement of nymphal deer ticks onto the treated skin of ten human volunteers. In hours five to eight of the test, average repellency decreased from 99% to 82%. Ticks crawled without hesitation onto the untreated skin of all controls.

The product label submitted for Formula No. 13349-14 claims a six-hour repellency for deer ticks. A deer tick repellent should demonstrate a minimum of 95% protection from bites. According to this study, Skin-So-Soft Bug Guard Plus IR3535 Expedition Insect Repellent SPF 0 - Pump Spray will provide 95% (94.8% rounded to a whole number) protection from deer ticks for up to six hours. However, there is not adequate protection ≥7 hours.

SPF 15 Insect Repellent Pump Spray Formula 16684-01 was 100% effective for a minimum of four hours in repelling the movement of nymphal deer ticks onto the treated skin of ten human volunteers. In hours five to eight of the test, repellency ranged from 20.5-100% among all subjects. Ticks crawled without hesitation onto the untreated skin of all controls.

However, efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from deer ticks. Therefore, this test should be repeated with Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300
MRID 45476001

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 94

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 0 2 2002

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature:
Date: APR 0 2 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 0 2 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 0 2 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist Robyn Rose 11/4/02

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359107
TEST MATERIAL:	13349-14 (A) SPF 0 Pump
STUDY NO:	0400-059-0079 (A)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901-5605
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dilon Heights Ave, Baltimore, MD 21228-1199
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Biting Midges
AUTHOR:	Niketas Spero
STUDY COMPLETED:	January 31, 2001
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

Two field tests were conducted in Florida to determine the efficacy of 13349-14 (A) SPF 0 Pump to repel biting midges (primarily *Culicoides furens* and *C. barbosai*). Eight-hour tests were conducted on two consecutive days, using ten volunteers each day. A 250 cm^2 area of exposed skin on one arm of each subject was treated with 0.48 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one arm of two additional control subjects was exposed for five minutes at half-hour intervals until the midge landing rate had peaked, after which exposure was continuous. Previous monitoring had determined that peak midge activity was limited to an approximate two-hour window. Therefore, to determine repellency eight hours after application, the test material was applied at least six hours prior to expected peak midge activity. Subjects

with treated arms were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two midge bites occurring within a thirty-minute period.

RESULTS SUMMARY

Based on a first confirmed bite test ,no breakdowns occurred on any subject during either test session. There was little midge activity during the first six hours of the test. Activity increased during the final two hours, but was still generally below 1 landing/minute. On Day 1, one control recorded 17 landings during the final one and one-half hours of the test; the other control recorded 8 landings during the same period. On Day 2, one control recorded 35 landings in the final 65 minutes, and the other recorded 71 landings in the final 69 minutes.

TABLE 1. Bite Times (Session 1) Heliopad, Pine Island Florida		
Test Subject	**Time of First Confirmed Bite (Hours & Minutes)**	**Time of First Bite (Hours and Minutes)**
1	> 8 Hr - 0 Min	> 8 Hr - 0 Min
2	> 8 Hr - 0 Min	> 8 Hr - 0 Min
3	> 8 Hr - 0 Min	> 8 Hr - 0 Min
4	> 8 Hr - 0 Min	> 8 Hr - 0 Min
5	> 8 Hr - 0 Min	> 8 Hr - 0 Min
6	> 8 Hr - 0 Min	> 8 Hr - 0 Min
7	> 8 Hr - 0 Min	> 8 Hr - 0 Min
8	> 8 Hr - 0 Min	4 Hr - 8 Min
9	> 8 Hr - 0 Min	> 8 Hr - 0 Min
10	> 8 Hr - 0 Min	> 8 Hr - 0 Min
Avg	> 8 Hr - 0 Min	> 7 Hr - 37 Min

Table 1 was copied from MRID 453591-07 page 9 of 131

TABLE 2. Bite Times (Session 3) Heliopad, Pine Island Florida		
Test Subject	***Time of First Confirmed Bite (Hours & Minutes)***	***Time of First Bite (Hours and Minutes)***
1	> 8 Hr - 0 Min	7 Hr - 49 Min
2	> 8 Hr - 0 Min	> 8 Hr - 0 Min
3	> 8 Hr - 0 Min	> 8 Hr - 0 Min
4	> 8 Hr - 0 Min	> 8 Hr - 0 Min
5	> 8 Hr - 0 Min	> 8 Hr - 0 Min

Test Subject	Time of First Confirmed Bite (Hours & Minutes)	Time of First Bite (Hours and Minutes)
6	> 8 Hr - 0 Min	7 Hr - 32 Min
7	> 8 Hr - 0 Min	> 8 Hr - 0 Min
8	> 8 Hr - 0 Min	> 8 Hr - 0 Min
9	> 8 Hr - 0 Min	1 Hr - 45 Min
10	> 8 Hr - 0 Min	> 8 Hr - 0 Min
Avg	> 8 Hr - 0 Min	> 7 Hr - 19 Min

Table 2 was copied from MRID 453591-07 page 10 of 131

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that, at the population densities in the test areas, 13349-14 (A) SPF 0 Pump provided complete protection from midge bites for all subjects at both locations during both days of testing.

REVIEWER'S CONCLUSIONS

In two 8-hour field tests using human subjects, 13349-14 (A) SPF 0 Pump was evaluated for protection against biting midges (*Culicoides furens* and *C. barbosai*). OPPTS 810.3300 states that a product may be registered for repelling biting flies (including midges) if it provides 1 to 3 hours of protection. A biting pressure of at least one landing in five minutes is recommended by OPPTS 810.3700 (Draft). The recommended landing rate was achieved during the last hour or more of testing on Day 2 (Session 3), but did not occur on Day 1 (Session 1) of testing. No information was reported for a Session 2. It is acceptable that the test material was applied so that peak midge activity occurred during the end of the test period when the repellent would be expected to be least effective.

This test was conducted based on the "first confirmed bite test". Tests should be conducted based on a 95% reduction in bites. Based on the raw data provided, it can be concluded that 95% reduction in bites was achieved during this study. Although at least a 95% reduction in bites was achieved on the treated test subjects, biting pressure was only acceptable during Day 2 of testing. Since the overall landing rate was only acceptable for one test, a second test should be conducted to verify the efficacy of 13349-14 (A) SPF 0 Pump for an eight-hour repellency against biting midges.

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not

affect on protection from biting midges. Therefore, this test should be repeated in two locations using the end-use product in areas with a biting pressure of at least one bite/land per five minute exposure period.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359107

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 96

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: _____

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359104
TEST MATERIAL:	13349-14 (A) SPF 0 Pump
STUDY NO:	0400-059-0078 (A)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	January 30, 2001
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

An eight-hour field test using 10 volunteers was conducted at Stuttgart High School in Stuttgart, Arkansas to determine the efficacy of 13349-14 (A) SPF 0 Pump to repel mosquitoes (primarily *Anopheles quadrimaculatus* and *Psorophora columbiae*). Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.48 mL of the test material (1.7 mg/cm^2), making a total of 20 test sites. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals until the late stages of the test, during which exposure was continuous. One of the controls also received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Control landings were monitored for 8.5 hours. Previous monitoring had determined that the mosquitoes were only active for about one hour, with landing rates of 1 to 10 per minute

during that period. Therefore, to determine repellency up to eight hours after application, the test material was applied seven hours prior to the expected activity period. Subjects with treated limbs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was based on the first confirmed bite test and was defined as two mosquito bites occurring within a thirty-minute period.

RESULTS SUMMARY

Breakdown based on the first confirmed bite did not occur 12 of the 20 test sites, with 9 of those 12 receiving no bites at all (Table 1). For the remaining sites, breakdown times ranged from 7 hours and 5 minutes to 8 hours and 0 minutes. No protection was claimed for seven sites since breakdown occurred prior to the period of high mosquito activity. The control whole-body mosquito landing count was 0 for the first 7 hours of the test, increasing to 45 landings at 8 hours and 57 at 8.5 hours. Control legs had comparable activity, with a total of 2 landings/five minutes at 7 hours, 5 landings/five minutes at 7.5 hours, 51 landings/five minutes at 8 hours, and 41 landings/five minutes at 8.5 hours.

TABLE 1. Mosquito biting times

Test subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	7 hr 30 min	7 hr 30 min
2/arm	>8 hr	7 hr 56 min
3/arm	7 hr 21 min	7 hr 21 min
4/arm	>8 hr	>8 hr
5/arm	7 hr 45 min	7 hr 45 min
6/arm	7 hr 22 min	7 hr 22 min
7/arm	>8 hr	>8 hr
8/arm	7 hr 5 min	7 hr 5 min
9/arm	>8 hr	>8 hr
10/arm	7 hr 12 min	7 hr 12 min
Avg/arm	7 hr 37 min	7 hr 31 min
1/leg	>8 hr	8 hr 0 min
2/leg	>8 hr	>8 hr
3/leg	7 hr 26 min	7 hr 26 min
4/leg	>8 hr	>8 hr
5/leg	>8 hr	>8 hr
6/leg	>8 hr	7 hr 51 min

7/leg	>8 hr	>8hr
8/leg	7 hr 15 min	7 hr 15 min
9/leg	>8 hr	>8 hr
10/leg	>8 hr	>8 hr
Avg/leg	7 hr 50 min	7 hr 50 min
Avg/arm & leg	7 hr 44 min	7 hr 41 min

REVIEWER'S CONCLUSIONS

OPPTS 810.3300 states that a product should generally provide a minimum of 2-3 hours protection time against mosquitoes, depending on the biting pressure. The test material in this study had to be applied well before the time of peak mosquito activity because the landing rate of five landings in five minutes recommended by OPPTS 810.3700 (Draft) on the control subjects was not achieved for most of the test period. The recommended biting pressure of 5 landings/5 minutes only occurred eight hours after application of the test material.

Duration of repellency should be based on time to first bite or 95% reduction in bites. It is difficult to interpret the submitted data based on a 95% reduction in bites; therefore, duration of repellency should be based on the average time to first bite. The average time to first bite in this study was approximately 7 hours and 41 minutes from test initiation. However, this data is insufficient to conclude a duration of repellency since biting pressure was only adequate at approximately the same time the repellent failed. Therefore, additional studies are needed to determine duration of effective repellency for 13349-14 (A) SPF 0 Pump.

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359104

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 96

Primary Reviewer:
Eric B. Lewis, M.S

Signature: Eric B. Lewis
Date: APR 12 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: P. H. Reno
Date: APR 12 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 12 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 12 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359105
TEST MATERIAL:	13349-14 (A) SPF 0 Pump
STUDY NO:	0400-059-0077 (A)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 8, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

An eight-hour field test using 10 volunteers was conducted in Butterfield Island, Maine to determine the efficacy of 13349-14 (A) SPF 0 Pump to repel mosquitoes (primarily *Aedes intrudens*). Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.48 mL of the test material (1.7 mg/cm^2), making a total of 20 test sites. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals throughout the test. One of the controls also received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Subjects with treated limbs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two mosquito bites occurring within a thirty-minute period.

RESULTS SUMMARY

There was no breakdown based on the first confirmed bite test on any of the 20 test sites at any time during the test (Table 1). The control whole-body mosquito landing count ranged from 25 to 77/minute, while landings on control legs ranged from 5 to 63/five minutes.

TABLE 1. Mosquito biting times

Test subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	>8 hr	>8 hr
2/arm	>8 hr	>8 hr
3/arm	>8 hr	> 8 hr
4/arm	>8 hr	>8 hr
5/arm	>8 hr	>8 hr
6/arm	>8 hr	>8 hr
7/arm	>8 hr	>8 hr
8/arm	>8 hr	>8 hr
9/arm	>8 hr	>8 hr
10/arm	>8 hr	>8 hr
Avg/arm	> 8 hr	> 8 hr
1/leg	>8 hr	>8 hr
2/leg	>8 hr	>8 hr
3/leg	>8 hr	>8 hr
4/leg	>8 hr	>8 hr
5/leg	>8 hr	>8 hr
6/leg	>8 hr	>8 hr
7/leg	>8 hr	>8hr
8/leg	>8 hr	>8 hr
9/leg	>8 hr	7 hr 25 min
10/leg	>8 hr	5 hr 33 min
Mean	> 8 hr	7 hr 39 min
Avg/arm & leg	> 8hr	7 hr 50 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 13349-14 (A) SPF 0 Pump provided eight-hours of protection from mosquito bites for 20 of the 20 test sites.

REVIEWER'S CONCLUSIONS

In a field test, 13349-14 (A) SPF 0 Pump provided protection from mosquito bites on 10 subjects for slightly less than 8 hours. The control whole-body mosquito landing count ranged from 25 to 77/minute, while landings on control legs ranged from 5 to 63/five minutes. OPPTS 810.3300 states that a mosquito repellent should generally provide a minimum of 2-3 hours protection time, depending on the biting pressure. The results of this study indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for 13349-14 (A) SPF 0 Pump claims an eight-hour repellency against mosquitoes. Duration of repellency should be based on time to first bite or 95% reduction in bites. The raw data shows that the time to first bite is slightly less than 8 hours; however, at least a 95% reduction in bites was achieved at 8 hours post treatment.

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from mosquitoes. Therefore, this test should be repeated in two environmentally distinct locations with mosquitoes from at least two different Genera using the end-use product

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359105

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 96

Primary Reviewer: Eric B. Lewis, M.S	Signature: Date:	Eric B. Lewis APR 12 2002
Secondary Reviewers: Patricia H. Reno, M.S.	Signature: Date:	 APR 12 2002
Robert H. Ross, M.S., Group Leader	Signature: Date:	 APR 12 2002
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson APR 12 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359106
TEST MATERIAL:	13349-14 (A) SPF 0 Pump
STUDY NO:	0400-059-0076 (A)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD, 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Black Flies
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 6, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Unacceptable because the end-use product was not used

TEST METHOD

Field tests were conducted near Lake Nicatous, Maine to determine the efficacy of 13349-14 (A) SPF 0 Pump to repel black flies (primarily *Simulium aureum* and *Prosimulium multidentatum*). Eight-hour tests were conducted on two consecutive days, using 10 different test subjects and 2 control subjects each day. The night before testing, subjects shoes were treated with Permonone® (0.k5% permethrin aerosol) to repel ticks. Subjects wore socks during testing and a 400 cm^2 area of exposed skin below one knee of each subject was treated with 0.77 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin below the knee of 2 control subjects was exposed for 5 minutes at approximately 30 intervals throughout the test period to verify biting pressure remained at 1-5/minute. Additionally, a whole-body count of black fly landings (time not specified) on one of the control subjects was taken at the beginning of the study and hourly

thereafter. Subjects with treated legs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two fly landings occurring within 30 minutes of each other. The second fly landing is considered a "confirmatory landing." A landing was defined as a fly remaining on the skin for at least 2 seconds. Test subjects moved about an area in pairs remaining approximately 1-2 meters apart. Data was reported as the average amount of time in hours and minutes to test termination.

RESULTS SUMMARY

Breakdown determined on the basis of the first confirmed bite occurred within eight hours on 11 of the 20 test subjects over the two days. On Day 1, the breakdown time ranged from 3 hours and 47 minutes to >8 hours, with an average of 5 hours and 53 minutes. On Day 2, breakdown time ranged from 4 hours and 1 minute to >8 hours, with an average of 6 hours and 45 minutes. The average time to first landing was 4 hours and 57 minutes on Day 1 and 4 hours and 53 minutes on Day 2. Fly landings on control subjects ranged from 3 to 24/five-minute exposure on Day 1, and from 3 to 33 landings/five-minute exposure on Day 2. Whole body counts for the control subjects ranged from 18 to 33 landings/minute on Day 1, and from 32 to 63 landings/minute on Day 2.

TABLE 1. *Fly landing times*

Test subject	Breakdown time	Time of first landing
Day 1		
1	>8 hr	6 hr 25 min
2	6 hr 6 min	6 hr 6 min
3	5 hr 53 min	4 hr 4 min
4	5 hr 34 min	0 hr 42 min
5	4 hr 44 min	4 hr 44 min
6	4 hr 50 min	4 hr 50 min
7	3 hr 47 min	2 hr 47 min
8	3 hr 53 min	3 hr 53 min
9	>8 hr	>8 hr
10	>8 hr	>8 hr
Mean	5 hr 53 min	4 hr 57 min
Day 2		
1	> 8 hr	2 hr 23 min
2	> 8 hr	0 hr 20 min
3	>8 hr	>8 hr

Test subject	Breakdown time	Time of first landing
4	>8 hr	>8 hr
5	>8 hr	6 hr 1 min
6	>8 hr	>8 hr
7	4 hr 1 min	2 hr 46 min
8	5 hr 16 min	5 hr 16 min
9	5 hr 9 min	5 hr 9 min
10	5 hr 2 min	2 hr 57 min
Mean	6 hr 45 min	4 hr 53 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 13349-14 (A) SPF 0 Pump provided good overall protection from black fly landings, with an average protection time of 5 hours and 53 minutes on Day 1 and 6 hours and 45 minutes on Day 2.

REVIEWER'S CONCLUSIONS

The study author based the duration of repellency on the first confirmed bite test. Duration of repellency should be based on time to first bite/landing or a 95% reduction in bites/lands. The raw data shows that the mean time to first bite is slightly less than 5 hours. This exceeds the minimum protection time of 3 hours specified by OPPTS 810.3300. The study author noted that there were four 5-minute exposure periods on Day 1 and one on Day 2 when the rate of five landings in five minutes recommended by OPPTS 810.3700 (Draft) was not achieved by one of the two control subjects. However, in each case the other control subject did achieve at least that rate, and none of the low rates occurred during consecutive test periods or during the last hour of either day, when the test material would have been least effective. The overall landing rate was therefore judged to be acceptable.

The product label submitted for 13349-14 (A) SPF 0 Pump claims a seven hour repellency against black flies. However, results of this study only support a claim of 5 hours of repellency. Therefore, the directions for use section of the label should advise this repellent be reapplied every 5 hours for protection from black flies.

Efficacy tests should be conducted with the end-use product. This test was conducted with SPF 0 Insect Repellent Pump Spray Formula 13349-14 which is not identical to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent. According to a list of the ingredients, a fragrance that is in Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent was not added to SPF 0 Insect Repellent Pump Spray Formula 13349-14. It is unknown if this fragrance affects the rate and duration of repellency. This fragrance may be attractive, repellent or have not affect on protection from black flies. Therefore, this test should be repeated in two locations

using the end-use product in areas with a biting pressure of at least five bites/lands per five minute exposure period.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359106

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 96

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 12 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: Patricia H. Reno
Date: APR 12 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 12 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 12 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance. OPPTS 810.3300
MRID NO:	45359008
TEST MATERIAL:	16360-23 (D) Aerosol
STUDY NO:	0400-059-0076 (D)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave. Baltimore, MD 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Black Flies
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 7, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Acceptable for a claim of 4 hours of repellency

TEST METHOD

A field test was conducted in Maine to determine the efficacy of 16360-23 (D) Aerosol to repel black flies (primarily *Simulium aureum* and *Prosimulium multidentatum*). Eight-hour tests were conducted on two consecutive days, using different sets of ten volunteers each day. A 400 cm^2 area of exposed skin below one knee of each subject was treated with 0.74 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin below the knee of two control subjects was exposed for five minutes at approximately thirty-minute intervals throughout the test period. Additionally, a whole-body count (time not specified) of black fly landings on one of the control subjects was taken at the beginning of the study and hourly thereafter. Subjects with treated legs were removed from the test after breakdown of the repellent. Breakdown was based on the first

confirmed bite test and was defined as two fly landings occurring within a thirty-minute period. A landing was defined as a fly remaining on the skin for at least two seconds.

RESULTS SUMMARY

On Day 1, the breakdown time ranged from 3 hours and 1 minute to >8 hours, with an average of 6 hours and 0 minutes and the average time to the first bite occurred after five hours. On Day 2, breakdown time ranged from 3 hours and 43 minutes to >8 hours, with an average of 5 hours and 28 minutes and the average time to first bite was 3 hours 36 minutes. Fly landings on the control subjects ranged from 3 to 24/five-minute exposure on Day 1, and from 3 to 33 landings/five-minute exposure on Day 2. Whole body counts for the control subjects ranged from 18 to 33 landings/minute on Day 1, and from 32 to 63 landings/minute on Day 2.

TABLE 1. Fly landing times

Subject	Breakdown time	Time of first landing
Day 1		
1	5 hr 24 min	5 hr 24 min
2	>8 hr	3 hr 10 min
3	7 hr 2 min	7 hr 2 min
4	5 hr 47 min	5 hr 47 min
5	4 hr 38 min	4 hr 38 min
6	3 hr 1 min	3 hr 1 min
7	> 8 hr	6 hr 27 min
8	5 hr 9 min	3 hr 44 min
9	>8 hr	>8 hr
10	4 hr 56 min	2 hr 52 min
Mean	6 hr	5 hr 1 min
Day 2		
1	3 hr 43 min	1 hr 46 min
2	4 hr 47 min	1 hr 2 min
3	6 hr 26 min	0 hr 49 min
4	>8 hr	5 hr 38 min
5	4 hr 44 min	4 hr 44 min
6	4 hr 19 min	2 hr 58 min
7	5 hr 28 min	5 hr 28 min
8	4 hr 54 min	4 hr 54 min

Subject	Breakdown time	Time of first landing
9	4 hr 52 min	4 hr 18 min
10	7 hr 25 min	4 hr 20 min
Mean	5 hr 28 min	3 hr 36 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 16320-23 (D) provided good overall protection from black fly landings, with an average protection time of 6 hours on Day 1 and 5 hours and 28 minutes on Day 2.

REVIEWER'S CONCLUSIONS

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The study author based the duration of repellency on the first confirmed bite test. Duration of repellency should be based on time to first bite/landing or a 95% reduction in bites/lands. The data shows that the mean time to first bite was 5 hours and 1 minute on Day 1 and 3 hours and 26 minutes on Day 2. This exceeds the minimum protection time of 3 hours specified by OPPTS 810.3300.

The results of this study indicate that the test material at the dosage tested provides an average protection time against black flies of at least four hours based on the average time to first bite. However, this study does not verify that 16360-23 (D) Aerosol will provide protection from black flies for 6 hours as the label states. Therefore, the label should recommend reapplying 16360-23 (D) Aerosol every 4 hours.

The study author noted that there were four 5-minute exposure periods on Day 1 and one on Day 2 when the rate of five fly landings in five minutes recommended by OPPTS 810.3700 (Draft) was not achieved by one of the two control subjects. However, in each case the other control subject did achieve at least that rate, and none of the low rates occurred during consecutive test periods or during the last hour of either day, when the test material would have been least effective. The overall landing rates were therefore considered acceptable.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359008

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 94

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 0 2 2002

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature:
Date: APR 0 2 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 0 2 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 0 2 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359007
TEST MATERIAL:	16360-23 (D) Aerosol
STUDY NO:	0400-059-0077 (D)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave. Baltimore, MD 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	November 9, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Conducted in accordance with requirements of 40 CFR Part 160
CLASSIFICATION:	Acceptable

TEST METHOD

An eight-hour field test using 10 volunteers was conducted in Butterfield Island, Maine to determine the efficacy of 16360-23 (D) Aerosol to repel mosquitoes. The predominant species collected during the test was *Aedes intrudens*. Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.46 mL of the test material (1.7 mg/cm^2), making a total of 20 test sites. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals. Additionally, one of the controls received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Subjects with treated limbs were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two mosquito bites occurring within a thirty-minute period.

RESULTS SUMMARY

There was no breakdown on 19 of the 20 test sites (Table 1). Breakdown time on the remaining site was 7 hours and 20 minutes. The control whole-body mosquito counts ranged from 25 to 77 landings/minute during the test. Control legs received 5 to 63 landings/5 minute exposure.

TABLE 1. Mosquito biting times

Subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	>8 hr	>8 hr
2/arm	>8 hr	>8 hr
3/arm	>8 hr	>8 hr
4/arm	>8 hr	>8 hr
5/arm	>8 hr	>8 hr
6/arm	>8 hr	>8 hr
7/arm	>8 hr	>8 hr
8/arm	>8 hr	>8 hr
9/arm	>8 hr	>8 hr
10/arm	>8 hr	>8 hr
Avg/arm	>8 hr	>8hr
1/leg	>8 hr	>8 hr
2/leg	>8 hr	>8 hr
3/leg	>8 hr	>8 hr
4/leg	>8 hr	>8 hr
5/leg	>8 hr	>8 hr
6/leg	>8 hr	>8 hr
7/leg	>8 hr	>8hr
8/leg	>8 hr	>8 hr
9/leg	>8 hr	>8 hr
10/leg	7 hr 20 min	1 hr 34 min
Avg/leg	7 hr 58 min	7 hr 20 min
Average	7 hr 59 min	7 hr 31 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 16320-23 (D) provided excellent protection (8 hours) from mosquito bites, providing an average protection time of 7 hours and 58 minutes.

REVIEWER'S CONCLUSIONS

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The study author based the duration of repellency on the first confirmed bite test. Duration of repellency should be based on time to first bite or a 95% reduction in bites. The data shows that the mean time to first bite was >8 hours for arms and >7 hrs 20 min for legs. A >95% reduction in bites was achieved for the 8 hours of repellency listed on the product label. This exceeds the minimum protection time of 3 hours specified by OPPTS 810.3300.

The results of this study indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray claims an eight hour repellency against mosquitoes and is acceptable.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359007

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 94

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 0 2 2002

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature: APR 0 2 2002
Date:

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross APR 0 2 2002
Date:

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR 0 2 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance. OPPTS 810.3300
MRID NO:	45359006
TEST MATERIAL:	16360-23 (D) Aerosol
STUDY NO:	0400-059-0078 (D)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Hieghts Ave, Baltimore, MD
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Mosquitoes
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	January 30, 2001
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Acceptable

TEST METHOD

An eight-hour field test using 10 volunteers was conducted in Arkansas to determine the efficacy of 16360-23 (D) Aerosol to repel mosquitoes (primarily *Anopheles quadrimaculatus* and *Psorophora columbiae*). Areas of exposed skin (250 cm^2 each) on one arm and one leg of each subject were treated with 0.46 mL of the test material (1.7 mg/cm^2), making a total of 20 test sites. The test material was applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one leg of two additional control subjects was exposed for five minutes at thirty-minute intervals until the late stages of the test, during which exposure was continuous. Additionally, one of the controls received a whole-body mosquito landing count (time not specified) at study start and hourly thereafter. Previous monitoring had determined that the mosquitoes were only active for about one hour, with landing rates of 1 to 10 per minute during that period. Therefore, to determine repellency up to eight hours after application, the test material was applied seven hours prior to the expected activity period. Subjects with treated limbs were removed from the test after breakdown of the repellent.

Breakdown was based on the first confirmed bite test and was defined as two mosquito bites occurring within a thirty-minute period.

RESULTS SUMMARY:

There was no breakdown on 15 of the 20 test sites, with 9 of those 15 receiving no bites at all (Table 1). For the remaining 5 sites, breakdown time ranged from 6 hours and 46 minutes to 7 hours and 40 minutes, but no protection was claimed for two of those sites since breakdown occurred prior to the period of high mosquito activity. The whole-body control received 0 landings during the first 7 hours of the test, followed by 21 landings at 8 hours. Control legs (combined) had comparable activity, with only 1 landing until 7 hours and 30 minutes, when 18 landings/five minutes occurred, followed by 50 landings/five minutes at 8 hours.

TABLE 1. Mosquito biting times

Subject/limb	Breakdown time (2 bites within 30 minutes)	Time of first bite
1/arm	>8 hr	>8 hr
2/arm	>8 hr	>8 hr
3/arm	7 hr 40 min	7 hr 40 min
4/arm	>8 hr	>8 hr
5/arm	7 hr 23 min	7 hr 23 min
6/arm	>8 hr	7 hr 23 min
7/arm	>8 hr	7 hr 27 min
8/arm	>8 hr	7 hr 52 min
9/arm	>8 hr	>8 hr
10/arm	>8 hr	>8 hr
Avg/arm	7 hr 54 min	7 hr 47 min
1/leg	7 hr 13 min	7 hr 13 min
2/leg	>8 hr	>8 hr
3/leg	6 hr 46 min	6 hr 46 min
4/leg	>8 hr	>8 hr
5/leg	>8 hr	7 hr 24 min
6/leg	>8 hr	7 hr 56 min
7/leg	>8 hr	>8hr
8/leg	>8 hr	7 hr 18 min
9/leg	7 hr 34 min	7 hr 34 min
10/leg	>8 hr	>8 hr
Avg/leg	7 hr 44 min	7 hr 37 min
Avg/arm & leg	7 hr 49 min	7 hr 42 min

STUDY AUTHOR'S CONCLUSIONS:

The study author concluded that 16320-23 (D) provided complete protection (8 hours) from mosquito bites for 15 of the 20 test sites, provided 7 hours and 23 minutes to 7 hours and 40 minutes of protection for 3 of 20 sites, and no protection for two sites. It was noted that the test subjects perspired profusely during the entire test period due to extreme temperature (83-96°F) and humidity (55-76%). As a result, some of the repellent may have washed from the subjects' skin, contributing to the breakdowns seen in this study.

REVIEWER'S CONCLUSIONS:

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The study author based the duration of repellency on the first confirmed bite test. Duration of repellency should be based on time to first bite or a 95% reduction in bites. The data shows that the mean time to first bite was 7 hr 47 min for arms and >7 hrs 37 min for legs. Since biting pressure was zero until 7.5 to 8 hours post treatment, a >95% reduction in bites could not be determined.

The product label submitted with MRID 45359006 claims an eight hour repellency against mosquitoes. Although the average time to first bite reported in Table 1 was slightly less than 8 hours, it can be assumed that an average time to first bite was at least 8 eight post application since five treated arms and four treated legs provided >8 hours of protection from mosquito bites. The results of this study indicate that the test material at the dosage tested is effective in repelling mosquitoes from human skin for the specified period. The product label submitted for Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray claims an eight hour repellency against mosquitoes and is acceptable.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359006

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 94

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR [illegible] 2002

Secondary Reviewers:
Dennis M. Opresko, Ph.D.

Signature:
Date: APR 3 [illegible] 2002

Robert H. Ross, M.S., Group Leader

Signature:
Date: APR [illegible] 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR [illegible]

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance, OPPTS 810.3300
MRID NO:	45359009
TEST MATERIAL:	16360-23 (D) Aerosol
STUDY NO:	0400-059-0079 (D)
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Insect Control & Research, Inc., 1330 Dillon Heights Ave, Baltimore, MD 21228
TITLE OF REPORT:	Evaluation of the Efficacy of a Personal Repellent Against Biting Midges
AUTHOR:	Niketas C. Spero
STUDY COMPLETED:	January 31, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	Conducted in accordance with requirements of 40 CFR Part 160, except subpart 160.130(e)
CLASSIFICATION:	Acceptable for a claim of 4 hours of repellency

TEST METHOD

Three field tests were conducted in Pine Island, Florida to determine the efficacy of 16360-23 (D) Aerosol to repel biting midges (primarily *Culicoides furens* and *C. barbosai*). Eight-hour tests were conducted on each of three consecutive days, using ten volunteers each day. Day 1 testing was conducted at Heliopad on Pine Island, FL and Days 2 and 3 occurred at Conifer Lake, Pine Island, FL.

A 250 cm^2 area of exposed skin on one arm of each subject was treated with 0.46 mL of the test material (1.7 mg/cm^2), applied via a needleless syringe and spread evenly over the area with a gloved fingertip. An equal area of untreated skin on one arm of two additional control subjects was exposed for five minutes at thirty-minute intervals until the midge landing rate had peaked, after which exposure was continuous. Previous monitoring had determined that peak midge activity was limited to an approximate two-hour window. Therefore, to determine repellency eight hours after application, the test material was applied at least six hours prior to expected peak midge activity. Subjects with treated arms were removed from the test after breakdown of the repellent. Breakdown was based on the first confirmed bite test and was defined as two midge bites occurring within a thirty-minute period.

RESULTS SUMMARY

In all three tests, control subjects experienced at least one landing/minute during the last hour of testing which is adequate biting pressure to conduct this test. On Day 1, breakdown occurred on 1 of the 10 test subjects after 7 hours and 40 minutes; all other subjects were protected for the duration of the test. On Day 2, breakdown times ranged from 1 hour and 20 minutes to >8 hours, with an average of 6 hours and 0 minutes. On Day 3, breakdown times ranged from 1 hour and 0 minutes to >8 hours, with an average of 3 hours and 10 minutes.

TABLE 1. Midge biting times

Subject	Breakdown time (2 bites within 30 minutes)	Time of first bite
Day 1		
	>8 hr	>8 hr
2	>8 hr	>8 hr
3	>8 hr	>8 hr
4	>8 hr	>8 hr
5	7 hr 40 min	7 hr 40 min
6	>8hr	>8hr
7	>8 hr	>8hr
8	>8 hr	>8 hr
9	>8 hr	>8 hr
10	>8 hr	6 hr 8 min
Mean	7 hr 58 min	7 hr 49 min
Day 2		
1	7 hr 34 min	7 hr 34 min
2	1 hr 20 min	1 hr 20 min
3	1 hr 37 min	1 hr 37 min
4	>8 hr	>8 hr
5	7 hr 48 min	1 hr 37 min
6	>8 hr	1 hr 37 min
7	>8 hr	>8 hr
8	>8 hr	>8 hr
9	>8 hr	1 hr 35 min
10	1 hr 39 min	1 hr 39 min
Mean	6 hr 0 min	4 hr 6 min

Day 3		
1	1 hr 28 min	1 hr 28 min
2	1 hr 31 min	1 hr 31 min
3	1 hr 0 min	1 hr 0 min
4	3 hr 9 min	3 hr 9 min
5	1 hr 59 min	1 hr 59 min
6	3 hr 16 min	3 hr 16 min
7	2 hr 10 min	2 hr 10 min
8	>8 hr	>8 hr
9	>8 hr	1 hr 34 min
10	1 hr 9 min	1 hr 9 min
Mean	3 hr 10 min	2 hr 32 min
Mean of Days 1, 2 & 3	5 hr 42 min	4 hr 44 min

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that 16320-23 (D) provided complete protection from midge bites for 9 of 10 subjects on Day 1, when midge population densities were light. It provided average breakdown times of 6 hours and 0 minutes and 3 hours and 10 minutes on Days 2 and 3, respectively, when midge population densities were much higher. Individual protection times were variable on Days 2 and 3, ranging from 1 hour and 0 minutes to >8 hours.

REVIEWER'S CONCLUSIONS

OPPTS 810.3300 states that a product may be registered for repelling biting flies (including midges) if it provides 1 to 3 hours of protection. The results of this study indicate that the test material at the dosage tested is effective in repelling biting midges from human skin for over 3 hours. The recommended landing rate of one bite/landing per 5 minute exposure was exceeded during the time of peak midge activity for each test, which occurred when the test material would likely be least effective. The overall landing rate was therefore judged acceptable.

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The product label submitted with MRID 45359009 claims a six hour repellency against biting midges. However, this study did not demonstrate six hours of repellency of biting midges. The study author based the duration of repellency on the first confirmed bite test. Duration of repellency should be based on time to first bite or a 95% reduction in bites. The overall mean time to first bite occurred approximately 4 hr 44 min after application of the test material. However, the mean time to first bite was < 4 hours after exposure in half of the subjects tested.

It can be concluded from this study that 16360-23 (D) Aerosol will provide an average of four hours of protection from biting midges. Therefore the label should recommend reapplication of Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray every four hours for protection against biting midges. Since sand flies and no-seeums are considered

synonymous common names to biting midges, it is also acceptable to claim four hours of repellency against these insects.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300

MRID 45359009

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 94

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 30 2002

Secondary Reviewers:
Dennis M. Onresko, Ph.D.

Signature:
Date: OCT 30 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 30 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: OCT 30 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

DATA EVALUATION RECORD

EPA Reviewer: Robyn I. Rose, Entomologist

Reviewed by Eric B. Lewis and Patricia H. Reno of Oak Ridge National Laboratory, Oak Ridge, TN 37830

STUDY TYPE:	Product Performance. OPPTS 810.3300
MRID NO:	45476001
TEST MATERIAL:	Insect Repellent Aerosol Spray, Formula No. 16360-23
STUDY NO:	AV0002c
SPONSOR:	Avon Products, Inc., Avon Place, Suffern, NY 10901
TESTING FACILITY:	Benzon Research, 208 Burnt House Rd, Carlisle, PA 17013
TITLE OF REPORT:	Repellency of Avon Insect Repellent Aerosol Spray Against Nymphal *Ixodes scapularis* Ticks
AUTHOR:	Gray L. Benzon, Ph.D
STUDY COMPLETED:	December 15, 2000
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE	The study was conducted in compliance with 40 CFR Part 160
CLASSIFICATION:	Acceptable

TEST METHOD

Laboratory tests were conducted to determine the efficacy of Avon Insect Repellent Aerosol Spray Formula No. 16360-23 to repel the movement of nymphal deer ticks (*Ixodes scapularis*) onto human skin. A 25 cm^2 area of skin on the medial forearm of 10 volunteers was treated with 42.5 mg of the test material (1.7 mg/cm^2). Just prior to treatment, the test material was sprayed into a container, applied using a variable pipette, and evenly spread across the test area. A similar area of untreated skin served as a control. The ticks were placed in test plates fabricated from polystyrene Petri dish lids with a 2.54-cm diameter hole in the center of the lid. A removable patch of paper towel was used to prevent ticks from escaping through the hole between challenges.

At 60-minute intervals over 8 hours (two subjects were tested every 30 minutes for the first four hours and every 60 minutes thereafter) the treated and control areas were each challenged by placing a test plate containing 10±2 ticks onto the skin for 60 seconds, and the number of tick contacts was determined. A contact was counted if the tick moved from the test plate completely onto the skin exposed through the hole in the center of the test plate and remained there for at

least five seconds. Ticks that remained on the skin for at least five seconds but exhibited certain retreat behaviors, e.g., rapid movement with multiple direction changes and immediate exit upon re-contacting the plate, were not counted as contacts. At the end of the 60-second challenge, the plate was removed from the skin and any ticks remaining on the skin were returned to the test plate

RESULTS SUMMARY

According to the study author, the test material provided 100% repellency during all intervals in eight of ten subjects (Table 1). In the remaining two subjects, a few tick contacts occurred during hours five through eight. The mean repellency was over 95% at all times. Ticks crawled without hesitation onto the untreated skin of all subjects.

Table 1. Percent repellency of Formula 16360-23

		Hours Post-Treatment							
Subject	$CP_{control}$ [a]	1	2	3	4	5	6	7	8
1	56.3	100	100	100	100	100	100	100	100
2	41.4	100	100	100	100	100	100	100	100
3	50.6	100	100	100	100	100	100	100	100
4	40.9	100	100	100	100	100	100	100	100
5	42.5	100	100	100	100	100	100	100	100
6	40.9	100	100	100	100	87.8	87.8	87.8	87.8
7	45.6	100	100	100	100	100	100	100	100
8	50.3	100	100	100	100	90.1	100	90.1	90.1
9	35.0	100	100	100	100	100	100	100	100
10	45.3	100	100	100	100	100	100	100	100
Mean		100	100	100	100	97.8	98.8	96.8	97.8

[a] Control Contact Percentage ($CP_{control}$) for each subject = sum of ticks on control skin ÷ sum of ticks exposed to control skin x 100

% Repellency for any post-treatment interval = 100 - (sum of contacts on treated skin ÷ sum of ticks exposed to treated skin x 10,000) - $CP_{control}$

STUDY AUTHOR'S CONCLUSIONS

The study author concluded that for 80% of the subjects, Formula 16360-23 applied at a rate of 1.7 mg/cm^2 was 100% effective in preventing the movement of deer ticks onto treated skin for at least eight hours post-treatment.

REVIEWER'S CONCLUSIONS

This test was conducted with 16360-23 (D) Aerosol which has the identical formulation to Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray. The results of the study indicate that the test material at the dosage tested is effective in repelling ticks from

human skin for a minimum of four hours, and in most subjects for eight hours. This exceeds the minimum acceptable protection time of one hour specified in OPPTS 810.3300. The product label submitted for Insect Repellent Aerosol Spray Formula No. 16360-23 claims an eight-hour repellency for deer ticks. This test resulted in a >95% repellency of deer ticks for eight hours. Therefore, it is acceptable to state an eight-hour duration of repellency on the Skin-So-Soft Bug Guard Plus IR3535® Expedition Insect Repellent - Aerosol Spray label.

DATA EVALUATION RECORD

BETA ALANINE, N-ACETYL-N-BUTYL-, ETHYL ESTER

STUDY TYPE: Product Performance, OPPTS 810.3300
MRID 45476001

Prepared for

Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 95

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: APR 10 2002

Secondary Reviewers:
Patricia H. Reno, M.S.

Signature: P. H. Reno
Date: APR 10 2002

Robert H. Ross, M.S., Group Leader

Signature:
Date: APR 10 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L. A. Wilson
Date: APR

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Department of Energy under contract number DE-AC05-00OR22725

13544

R142809

Chemical: .beta.- Alanine, N-acetyl-N-butyl-, ethyl ester

PC Code: 113509
HED File Code: 41600 BPPD Other
Memo Date: 11/4/2002
File ID: DPD277712
Accession #: *000-00-9002*

HED Records Reference Center
5/2/2007